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DOES AN EXTENDED STROKE UNIT SERVICE WITH EARLY SUPPORTED DISCHARGE HAVE ANY EFFECT ON BALANCE OR WALKING SPEED?

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Objective: **To evaluate the effect of an extended stroke unit service with early supported discharge on balance and walking speed, and to explore the association between initial leg paresis, initial movement ability and balance one year after stroke.**

Design: **A randomized controlled trial comparing early supported discharge with ordinary stroke unit service.**

Patients: **A total of 62 eligible patients after stroke.**

Methods: **The outcome measures were Berg Balance Scale and walking speed at 1, 6, 26 and 52 weeks after stroke.**

Results: **We found no significant differences between the 2 groups during follow-up. There was a significant improvement on Berg Balance Scale ($p = 0.013$) and walking speed ($p = 0.022$) in the early supported discharge group, but not in the ordinary service group, from 1 to 6 weeks' follow-up. All patients with initial severe leg paresis suffered from poor balance one year after the stroke. The odds ratio for poor balance was 42.1 (95% confidence interval; 3.5–513.9) among patients with no initial walking ability.**

Conclusion: **These results do not conclusively indicate that early supported discharge has an effect on balance. A strong association was found between initial severe leg paresis, initial inability to walk and poor balance after one year.**

Key words: Stroke, posture, gait, rehabilitation.

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INTRODUCTION

Effective stroke unit care with early mobilization improves functional outcome after stroke (1, 2), however, increased risk of falling is a major problem among patients after stroke (3), and impaired balance is one of the main reasons for falling (4). It is beneficial to provide further intensive exercise therapy in the subacute and chronic phase (5), and a programme of functional exercises in the patient's home or in an outpatient clinic, to improve both balance and walking speed after stroke (6–8).

Patients after stroke conventionally undergo a substantial part of their rehabilitation in hospital or rehabilitation clinics. A new kind of service has been developed during the last decade that offers patients early supported discharge (ESD), namely early discharge from hospital with rehabilitation at home. This service seems to reduce long-term dependency (9).

ESD is a composite intervention and comparing the results among various studies is difficult because ESD is conducted in different ways. Early discharge coordinated by a multidisciplinary team seems to be an important factor and the early exercise therapy in the patient's home is another factor that could be beneficial. This early exercise therapy in the patient's home could be defined as task-specific because it consists of functional tasks conducted in a functional setting. Task-specific training is recommended in further research to improve balance and functional outcome after a stroke (10, 11). Previous ESD trials have shown good functional outcome after stroke (9, 12, 13). Improved balance and walking speed may contribute to this result. However, it is still unknown whether ESD is beneficial to balance or walking speed.

Early prediction of functional outcome is another important topic in stroke management, and there is growing interest in conducting longitudinal studies to study the relationship between impairments and disability (3, 14, 15). Kollen et al. (15) claim that initial standing balance is more important than improvement in leg strength to achieve improvement in walking ability, while Jørgensen et al. (14) found a strong relationship between leg paresis and walking function. However, more knowledge about the relationship between specific body functions, such as initial leg paresis or movement ability, and activities, such as improvement in balance during mobility, would be useful in selecting optimal treatment strategies after stroke.

Two ESD trials have been conducted at the Stroke Unit at the University Hospital of Trondheim. The first trial showed reduced death and dependency for patients living in the city of Trondheim (12, 16) and the second trial showed no beneficial effect on functional outcome for patients living in a rural community (17). This study is based upon secondary outcomes from the trial evaluating early supported discharge for patients living in a rural community (17).

The aims of this study were to evaluate the effect of an extended stroke unit service (extended service) with ESD on balance and

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walking speed and to explore initial factors associated with balance one year after treatment in an acute stroke unit.

SUBJECTS AND METHODS

Subjects

Patients from 3 municipalities surrounding the city of Trondheim, who had been admitted to the Stroke Unit at Trondheim University Hospital, were screened for inclusion in the trial. Inclusion criteria were: diagnosis of an acute stroke according to the World Health Organization definition of stroke (18); Scandinavian Stroke Scale (SSS) (19) score greater than 2 points and less than 58 points; living at home before the stroke; inclusion within 72 hours after admission to the stroke unit and within 7 days after the onset of symptoms; able and willing to provide informed consent.

Research design

In the present study a randomized controlled design was used. Patients fulfilling the inclusion criteria were included and block randomized in blocks of 4, 6 or 8 patients, to either an ordinary stroke unit service (ordinary service) or the newly constructed extended service. The order of the blocks was randomly chosen. Sealed opaque envelopes were used for randomization and the procedure was carried out by an external office.

During the acute phase (the first 1–2 weeks) both groups received well-documented stroke unit care with focus on early mobilization combined with a standardized medical programme (20). The follow-up care for the ordinary service group is combined with further inpatient rehabilitation when more long-term rehabilitation is necessary or a follow-up programme organized by the primary healthcare system.

The extended service consisted of stroke unit treatment combined with a home-based programme of follow-up care co-ordinated by a mobile stroke team that offers early supported discharge and works in close co-operation with the primary healthcare system during the first 4 weeks after discharge. In contrast to the ordinary service, the intervention placed emphasis on early and intensive task-specific exercise therapy in the patients' home.

An independent and blinded assessor specially trained in the use of all the outcome measures performed all the assessments.

The Regional Committee on Medical Research Ethics approved the study protocol.

Evaluation

Baseline characteristics were recorded before randomization. All patients were followed-up at 1, 6, 26 and 52 weeks after onset of stroke.

The Berg Balance Scale (BBS) maximum score of 56 was used to measure balance (21, 22). On the multiple regression analysis BBS was dichotomized into good balance (BBS $\geq$45) versus poor balance and increased risk of falling (BBS <45) (22).

Walking speed was clocked across a 5 m length. The distance was walked twice at maximal walking speed. The means of the 2 trials were used as a test parameter representing the fast speed condition.

Motor function of the leg and the movement ability was assessed by use of the subscores from the SSS (19). The original leg score is graded in 5 categories: paralysis (0 point); can move, but not against gravity (2 points); raises leg with flexion in knee (4 points); raises leg straight but with reduced strength (5 points); and raises leg with normal strength (6 points). This item was categorized into 3 categories; severe paresis (0–2 points); moderate paresis (4–5 points) and no paresis (6 points). The originally movement score is also graded in 5 categories; confined to one's bed or wheelchair (0 point); sits without support (3 points); walks with support (6 points); walks with walking aid (9 points); walks 5 m without walking aid or support (12 points). This item was categorized into the following 3 categories; no walking ability (0–3 points), walks with support (6–9 points) and independent walking ability (12 points).

Statistical analysis

Baseline characteristics were compared using Mann-Whitney *U* test (ordinal data), *t*-test for independent samples (ratio data), or χ^2 tests (nominal data). Outcomes between the 2 groups at 1 week, 6 weeks, 26 weeks and 52 weeks' follow-up were compared using Mann-Whitney *U* test (ordinal data) and *t*-test for independent samples (ratio data).

Change within groups analysis were performed on those patients who had completed all assessments from 1 to 6 weeks, 1 to 26 weeks and 1 to 52 weeks by using Wilcoxon signed rank test on BBS and paired *t*-test on walking speed.

Differences in change between groups were analysed by Mann-Whitney *U* test on the BBS and by Student's *t*-test on walking speed. The change was calculated as the difference between the 6 week test minus the 1 week test, the 26 week test minus the 1 week test and the 52 week test minus the 1 week test.

Multiple logistic regression was used to analyse the association between initial leg paresis and initial movement ability as independent variables, and the dichotomized BBS score 52 weeks after stroke as the dependent variable, allowing adjustments for potential confounders such as age, sex, treatment group and number of days from onset of symptoms to hospital admission (23).

All the analysis was performed in the statistical programme of SPSS 13.0 for Windows and a *p*-value less than 0.05 was considered significant.

RESULTS

Figure 1 shows the flow of patients through the study and the reasons for exclusion and drop-out according to BBS. In all, 89 patients were screened for inclusion between 1 June 1999 and 15 June 2001. A total of 62 patients were included in the study and 31 patients were randomly allocated to the extended service group and 31 to the ordinary service group. In the ordinary service group there were 2 partial drops out at 1 week follow-up. At 6 weeks' follow-up, 1 of the patients who were lost to follow-up because of illness withdrew from the study and another patient died.

There were no significant differences between the 2 groups for any of the baseline characteristics (Table I).

Table II shows a significant difference in fast walking speed ($p = 0.043$) and a trend toward better BBS score ($p = 0.144$) in the ordinary stroke unit service group at 1 week follow-up. There were no significant differences in BBS score or walking speed between the 2 groups at any other time during follow-up.

Changes within the extended service group (Table III) showed a significant increase in the BBS score from 1 to 6 weeks ($p = 0.013$) and an almost significant increase in BBS score from 1 to 26 weeks ($p = 0.051$). In addition, there was a significant increase in walking speed from 1 to 6 weeks ($p = 0.022$), from 1 to 26 weeks ($p = 0.044$) and from 1 to 52 weeks ($p = 0.028$). There were no significant changes on BBS or walking speed at any time in the ordinary service group.

The differences in change between the 2 groups showed a trend toward greater improvement in the extended service group compared with the ordinary service group from 1 week follow-up to 6 weeks' follow-up ($p = 0.065$) and from 1 week follow-up to 26 weeks' follow-up ($p = 0.142$) on the BBS, but no differences in change between the 2 groups on fast walking speed.

Visual analysis of Figs. 2 and 3 show an initial improvement and a later decline on both BBS and fast walking speed.

In our study 36.9% of patients with no leg paresis, 48.4% of patients with moderate paresis and 100% of patients with severe

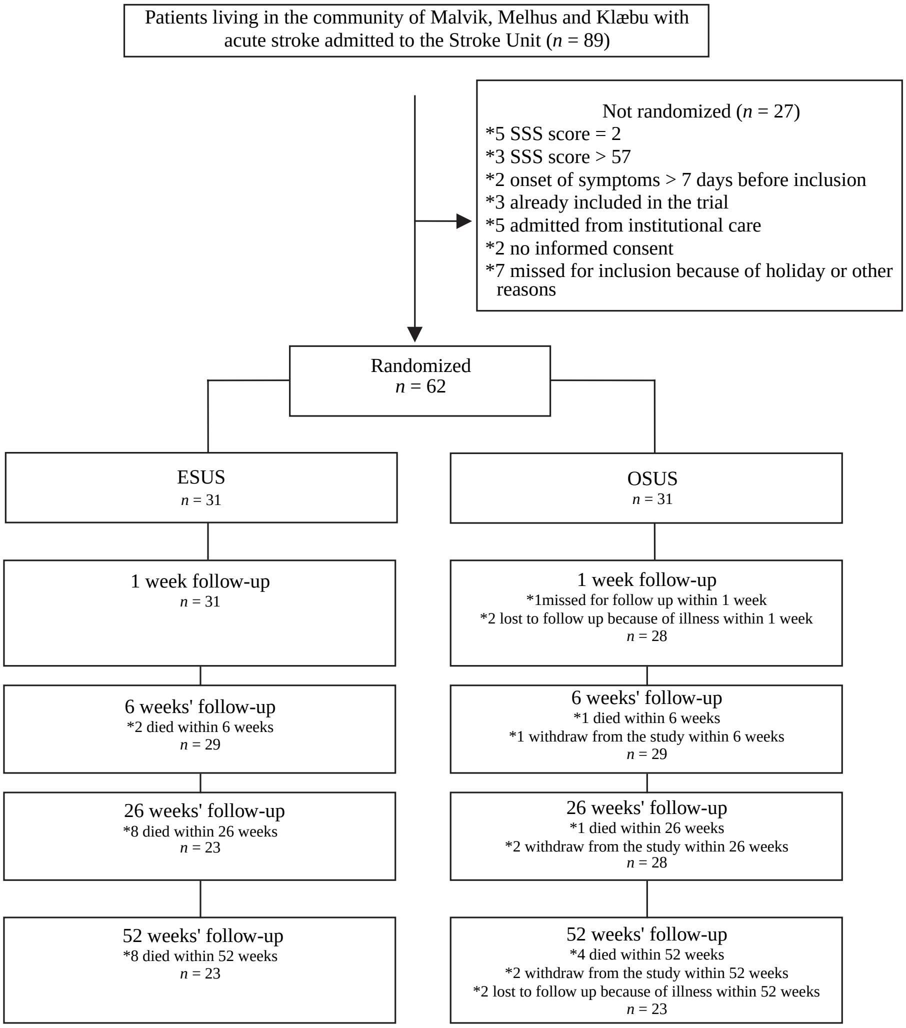

Fig. 1. Flow chart of patients randomized and followed-up with Berg Balance Scale. ESUS = extended stroke unit service; OSUS = ordinary stroke unit service; SSS = Scandinavian Stroke Scale.

leg paresis showed poor balance after one year. According to the movement item, 20.0% of patients with initial independent walking ability, 66.7% of patients able to walk with support and 90.9% of patients with no walking ability showed poor balance. Table IV shows the calculated odds ratio (OR) for poor balance among patients with initial leg paresis and reduced movement ability. Adjustment for potential confounders did not materially change the results, although the OR for poor balance became less significant among patients with initial leg paresis and more significant among stroke patients with reduced initial walking ability.

DISCUSSION

This study shows no significant differences between the extended service group and the ordinary service group on BBS or walking speed at any phase in the treatment. However, the extended service group had a greater improvement on both BBS and fast walking speed than the ordinary service group. The study also shows a strong association between initial severe leg paresis, initial inability to walk and poor balance.

The strength of this study is the randomized controlled design with a blinded assessor. In addition the study population is an unselected population. As shown in Fig. 1 70% of the patients admitted to the stroke unit met the criteria for inclusion in the trial. All the included patients received evidence-based stroke unit treatment according to the "gold standard" (20) and any improvement would have been in addition to the effect of this acute treatment.

There were few inhabitants in the 3 rural municipalities, and consequently a low number of people suffering from stroke. This was the principally reason for the small sample size. The small sample size and the low statistical power according to the primary outcome is the most important weakness of the present study (17). This leads to an increased risk of uneven distribution of potential confounders.

There is no data on BBS or walking speed at baseline, though at 1 week follow-up there was a significantly faster walking

Table I. *Baseline characteristics of patients allocated to extended stroke unit service (ESUS) and ordinary stroke unit service (OSUS)*

	ESUS ($n=31$)	OSUS ($n=31$)
Age (years), mean/median	76.9/77.0	76.3/76.0
Sex, number (%) male	16 (51.6)	17 (54.8)
Living alone number (%)	11(35.5)	15 (48.4)
Diagnosis number (%)		
Non-embolic infarction	18 (58.1)	20 (64.5)
Embolic infarction	5 (16.1)	8 (25.8)
Haemorrhage	7 (22.6)	3 (9.7)
Transient ischemic attack	1 (3.2)	0 (0.0)
Medical history, number (%)		
Transient ischemic attack	6 (19.4)	2 (6.5)
Stroke	2 (6.5)	1 (3.2)
Myocardial infarction	5 (16.1)	7 (22.6)
Atrial fibrillation	3 (9.7)	8 (25.8)
Hypertension	3 (9.7)	10 (32.3)
Diabetes	1 (3.2)	5 (16.1)
Functional state		
Scandinavian Stroke Scale, mean/median	45.4/46.0	41.5/46.0
Barthel Index, mean/median	57.7/55.0	54.0/55.0
Rankin Scale, mean/median	3.7/4.0	3.5/4.0

speed and a trend toward higher BBS score in the ordinary service group. The intervention cannot explain this difference because the patients were still in the stroke unit at this time and the main intervention started at discharge from the stroke unit. The small sample size and a not completely successful randomization have to account for this difference. In addition 3 patients were lost to follow-up in the ordinary service group at 1 week follow-up and may have caused additional uneven distribution. We assume that our analysis comparing groups at 6, 26 and 52 weeks may have been influenced by the initial difference between the 2 groups.

The BBS is measuring balance according to 14 functional tasks. Most of the tasks measure balance during sitting or standing position, and it will be a ceiling effect for patients with very mild stroke and only minor reduction in balance. However, walking speed will not suffer from this ceiling effect as the mean fast walking speed among patients in both groups were much slower than the usual fast walking speed among people at their age (24).

The cut-off on BBS between 44 and 45 points with an increased risk of falling for those with a BBS less than 45 points has been well documented (22), although Harries et al. (25) recommend clinicians to be cautious when using BBS to determine fall risk among patients with chronic stroke. The categorization of the leg and movement items on SSS is done in different ways in the literature. Jorgensen et al. (3) chose to dichotomize the leg item, while Jorgensen et al. (14) kept all 5 categories. There is a wide range of paresis, from total paralysis to a small reduction in strength. It is not likely that moderate paresis would be the same predictor as severe paresis and the categorization into 3 categories; no paresis, moderate paresis, and severe paresis appears to be clinically meaningful. Our results indicate different associations for these categories with severe leg paresis compared with those with moderate leg paresis.

Table II. *Differences between groups on Berg Balance Scale and fast walking speed assessed at 16, 26 and 52 weeks after stroke*

	ESUS	OSUS	*p*-value
1 week post-stroke			
Berg Balance Scale	($n=31$)	($n=28$)	
Mean (SD)	28.6 (21.4)	35.4 (21.4)	
Median (IQR)[1]	32.0 (4.0–50.0)	43.5 (18.5–54.8)	0.144
Fast walking speed (m/s)	($n=22$)	($n=22$)	
Mean (SD)[2]	0.78 (0.36)	1.03 (0.43)	0.043
6 weeks' post-stroke			
Berg Balance Scale	($n=29$)	($n=29$)	
Mean (SD)	33.9 (21.6)	35.4 (21.1)	
Median (IQR)[1]	46.0 (8.0–51.5)	42.0 (17.5–54.5)	0.464
Fast walking speed (m/s)	($n=21$)	($n=24$)	
Mean (SD)[2]	0.91 (0.31)	1.06 (0.46)	0.217
26 weeks' post-stroke			
Berg Balance Scale	($n=23$)	($n=28$)	
Mean (SD)	35.7 (20.6)	36.3 (20.2)	
Median (IQR)[1]	44.0 (19.0–53.0)	43.5 (23.0–55.0)	0.842
Fast walking speed (m/s)	($n=18$)	($n=22$)	
Mean (SD)[2]	1.02 (0.41)	1.15 (0.53)	0.406
52 weeks' post-stroke			
Berg Balance Scale	($n=23$)	($n=23$)	
Mean (SD)	33.1 (22.1)	36.0 (22.1)	
Median (IQR)[1]	43.0 (6.0–53.0)	45.0 (13.0–56.0)	0.440
Fast walking speed (m/s)	($n=15$)	($n=18$)	
Mean (SD)[2]	0.97 (0.41)	1.22 (0.48)	0.130

ESUS = extended stroke unit service; OSUS = ordinary stroke unit service; IQR = inter quartile range; SD = standard deviation; [1] Mann-Whitney *U* test; [2] Student's *t*-test.

Table III. *Changes within groups during follow-up on those patients who completed all assessments on Berg Balance Scale (BBS) and fast walking speed*

	ESUS			OSUS		
	n	Median (IQR)	Change within group *p*-value[1]	*n*	Median (IQR)	Change within group *p*-value[1]
BBS						
1 week	23	38.0 (9–51)		23	50.0 (20–55)	
6 weeks	23	47.0 (9–53)	0.013	23	53.0 (15–56)	0.815
26 weeks	23	44.0 (19–53)	0.051	23	48.0 (23–56)	0.897
52 weeks	23	43.0 (6–53)	0.824	23	45.0 (13–56)	0.505
	n	Mean (SD)	Change within group *p*-value[2]	*n*	Mean (SD)	Change within group *p*-value[2]
Fast walking speed (m/s)						
1 week	14	0.89 (0.35)		17	1.15 (0.39)	
6 weeks	14	1.05 (0.26)	0.022	17	1.21 (0.42)	0.287
26 weeks	14	1.11 (0.42)	0.044	17	1.28 (0.51)	0.122
52 weeks	14	1.02 (0.38)	0.028	17	1.23 (0.50)	0.243

ESUS = extended stroke unit service; OSUS = ordinary stroke unit service; IQR = inter quartile range; SD = standard deviation; [1]Wilcoxon signed rank test; [2]Paired *t*-test; Change within group is change from 1 to 6 weeks, from 1 to 26 weeks and from 1 to 52 weeks.

Although ESD trials seems to be beneficial for long-term dependency (9), it is still unknown which factors are the most efficient. In this study we focus on the early exercise therapy in the patient's home. Regarding dependency we suggest that the functional level can improve both by improvements in body function and by adjustment of the facilities. Improvement in balance measured by the BBS is most likely dependent on improvement within the body systems.

To our knowledge this is the first ESD trial reporting results on the BBS, while 3 other studies have reported walking speed (26–29), The results from those studies support our finding showing no difference in walking speed between the extended service and the ordinary service group. There could be at least 4 reasons for this result. In the first place both groups received stroke unit treatment which improves functional outcome (1, 2, 20) and makes it challenging to achieve further improvement. Secondly, we have not registered the content in detail and cannot be sure if the exercises were as task-specific and functional as intended, even though they were conducted in the patients' homes. Thirdly, the intensity of the exercise therapy may have been too low to give any additional effect. The fourth and last reason could be the additional emphasis on home safety intervention which may result in less challenge to the balance system and less improvement in balance and walking speed.

When each time point is analysed separately, the measurements will be from different subjects. It is of primary interest to analyse how subjects respond over time. The analysis of change within the 2 groups on those patients who are available through the whole study shows a significant improvement on BBS from 1 to 6 weeks' follow-up and from 1 to 26 weeks' follow-up in the extended service group. It also shows an improvement on fast

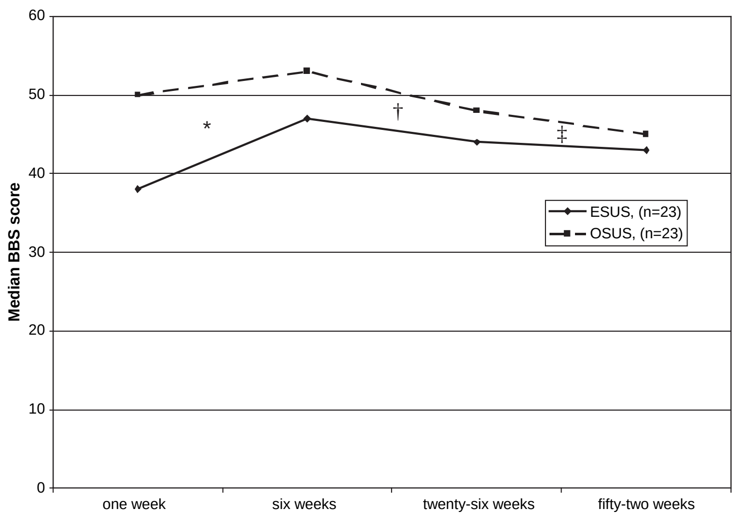

Fig. 2. How patients who have completed all assessments on Berg Balance Scale (BBS) respond over time. *Difference in change between groups from 1 week follow-up to 6 weeks' follow-up ($p = 0.065$). †Difference in change between groups from 1 week follow-up to 26 weeks' follow-up ($p = 0.142$). ‡Difference in change between groups from 1 week follow-up to 52 weeks' follow-up ($p = 0.400$). ESUS = extended stroke unit service; OSUS = ordinary stroke unit service.

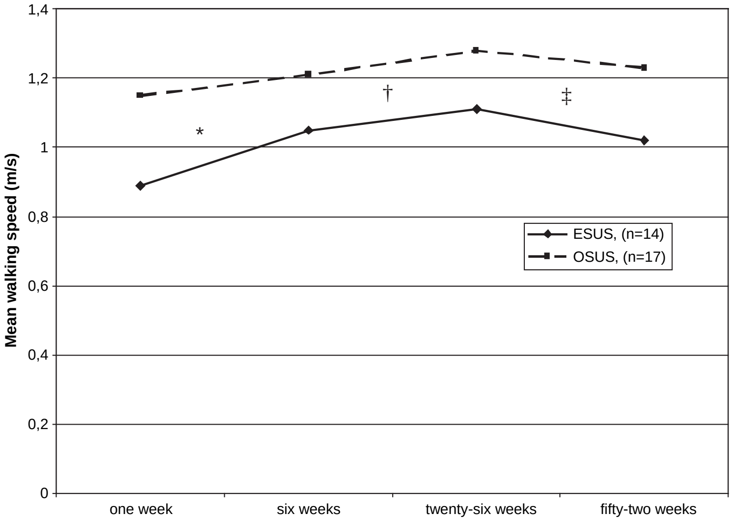

Fig. 3. How patients who have completed all assessments on fast walking speed respond over time. *Difference in change between groups from 1 week follow-up to 6 weeks' follow-up ($p = 0.224$). †Difference in change between groups from 1 week follow-up to 26 weeks' follow-up ($p = 0.494$). ‡Difference in change between groups from 1 week follow-up to 52 weeks' follow-up ($p = 0.557$). ESUS = extended stroke unit service; OSUS = ordinary stroke unit service.

walking speed from 1 to 6 weeks' follow-up, from 1 to 26 weeks' follow-up and from 1 to 52 weeks' follow-up. There were no similar improvements in the ordinary service group. One possible reason for no significant improvement from 1 to 6 weeks' follow-up in the ordinary service group may be due to the fact that this group was already close to the ceiling effect on BBS at 1 week follow-up.

When analysing the differences in change between the 2 groups from 1 week follow-up to each time point we found an almost significant greater improvement ($p = 0.065$) in the extended service group compared with the ordinary service group the first 6 weeks after the stroke and a trend toward greater improvement from 1 to 26 weeks ($p = 0.142$). This improvement might indicate that the extended service group is safer during transfer situations and consequently has reduced risk of falling, although these differences were not confirmed by the fast walking speed, and the trend toward greater improvement on BBS in the extended service group may also be due to the ceiling effect on BBS in the ordinary service group. However, it is difficult to make a final conclusion about the clinical relevance of this result because of the number of subjects is too small.

The visual analysis of Figs. 2 and 3 also shows an initial improvement and further decline in both balance and fast walking speed. This initial improvement and long-term decline in functional outcome and balance is confirmed by Langhammer & Stanghelle (30) in their study comparing Bobath treatment with a motor relearning programme.

Although the OR for poor balance could not be calculated for those with initial severe leg paresis, we will propose there is a strong association between those 2 variables. This result is in contrast to another study which found no association between leg paresis and falling when the results were adjusted for depression (3). One possible reason for this is the different ways of categorizing the leg item and the adjustment of different confounders. The Copenhagen Stroke Study has documented a strong relationship between initial leg paresis and recovery of walking function (14). Balance is an important component of walking function and this study supports our findings showing an association between initial severe leg paresis and poor balance.

Table IV. *Odds ratio (OR) and 95% confidence interval (CI) for poor balance one year after stroke associated with measures of initial leg paresis and initial movement ability*

Variable	Stroke patients (n)	Cases with BBS <45 (n)	OR (95% CI)[a]	p-value[a]
SSS leg score				
No paresis	11	4	1.0	
Moderate paresis	31	15	1.5 (0.3–7.3)	0.581
Severe paresis	4	4	nc	
SSS movement score				
Independent walking ability	15	3	1.0	
Walks with support	20	10	4.6 (0.8–26.5)	0.085
No walking ability	11	10	42.1 (3.5–513.9)	0.003

[a]OR adjusted for age, sex, treatment group and number of days from onset of symptoms to hospital admission; nc = not calculated because there were no cases with good balance; SSS = Scandinavian Stroke Scale; BBS = Berg Balance Scale.

The ability to move depends on trunk control and the strong association between early inability to move and poor balance after one year is confirmed by other studies that identify trunk control as en early predictor of functional outcome after stroke (31–33).

The results of this study of ESD with early rehabilitation in the patient's home does not conclusively indicate that ESD has an effect on balance. In addition, a strong association was found between initial severe leg paresis, initial inability to walk and poor balance after one year.

Further research should emphasize task-specific exercise therapy with a higher intensity in addition to ESD to enhance further improvement on balance and walking speed in order to facilitate an active life for the stroke patients.

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